

New Pharmacy Laws

Provided below are code sections that were amended or added during the 2004 Legislative Session. Unless otherwise indicated, all these provisions went into effect January 1, 2005. Summaries of the changes made to many of the code sections are provided in the January 2005 issue of *The Script* (http://www.pharmacy.ca.gov/publications/05_jan_script.pdf).

Business and Professions Code

4008. (a) Except as provided by Section 159.5, the board may employ inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation, may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

(b) Notwithstanding subdivision (a), a pharmacy inspector may inspect or examine a physician's office or clinic that does not have a permit under Section 4180 or 4190 only to the extent necessary to determine compliance with and to enforce either Section 4080 or 4081.

(c) (1) (A) A pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as a public officer, to arrest, without warrant, any person whenever the officer has reasonable cause to believe that the person to be arrested has, in his or her presence, violated a provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code.

(B) If the violation is a felony, or if the arresting officer has reasonable cause to believe that the person to be arrested has violated any provision that is declared to be a felony, although no felony has in fact been committed, he or she may make an arrest although the violation or suspected violation did not occur in his or her presence.

(2) In any case in which an arrest authorized by this subdivision is made for an offense declared to be a misdemeanor, and the person arrested does not demand to be taken before a magistrate, the arresting inspector may, instead of taking the person before a magistrate, follow the procedure prescribed by Chapter 5C (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code. That chapter shall thereafter apply with reference to any proceeding based upon the issuance of a citation pursuant to this authority.

(d) There shall be no civil liability on the part of, and no cause of action shall arise against, a person, acting pursuant to subdivision (a) within the scope of his or her authority, for false arrest or false imprisonment arising out of an arrest that is lawful, or that the arresting officer, at the time of the arrest, had reasonable cause to believe was lawful. An inspector shall not be deemed an aggressor or lose his or her right to self-defense by the use of reasonable force to effect the arrest, to prevent escape, or to overcome resistance.

(e) Any inspector may serve all processes and notices throughout the state.

(f) A pharmacy inspector employed by the board may enter a facility licensed pursuant to subdivision (c) or (d) of Section 1250 of the Health and Safety Code to inspect an automated drug delivery system operated pursuant to Section 4119 or 4119.1.

4022.5. (a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053.

(b) "Designated representative-in-charge" means a designated representative or a pharmacist who is the supervisor or manager of a wholesaler or veterinary food-animal drug retailer.

(c) This section shall become operative on January 1, 2006.

4026.5. "Good standing" means a license issued by the board that is unrestricted by disciplinary action taken pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

4030. "Intern pharmacist" means a person issued a license pursuant to Section 4208.

Effective January 1, 2007

4034. (a) "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug.

(b) A pedigree shall include all of the following information:

(1) The source of the dangerous drug, including the name, state license number, including California license number if available, and principal address of the source.

(2) The quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and if appropriate, the state license number, including a California license number if available, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

(4) A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate.

(c) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.

(d) The application of the pedigree requirement in pharmacies shall be subject to review during the board's sunset review to be conducted as described in subdivision (f) of Section 4001.

(e) This section shall become operative on January 1, 2007.

4040. (a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, or physician assistant who issues a drug order pursuant to Section 2746.51, 2836.1, or 3502.1, respectively, or the pharmacist who issues a drug order pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(2) Issued by a physician, dentist, optometrist, podiatrist, or veterinarian or, if a drug order is issued pursuant to Section 2746.51, 2836.1, or 3502.1, by a certified nurse-midwife, nurse

practitioner, or physician assistant licensed in this state, or pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (3) of subdivision (b) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

4043. (a) "Wholesaler" means and includes every person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or out-of-state distributor, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

(b) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

Effective January 1, 2006

4043. (a) "Wholesaler" means and includes a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

(b) This section shall become operative January 1, 2006.

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded medication to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(B) Ordering drug therapy-related laboratory tests.

(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(5) (A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(ii) Ordering drug therapy-related laboratory tests.

(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(B) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(ii) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) (A) Furnish emergency contraception drug therapy in accordance with either of the following:

(i) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(ii) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(B) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(C) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars (\$10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(D) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this paragraph.

(b) (1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.

(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

(c) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(d) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(e) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

4053. (a) Subdivision (a) of Section 4051 shall not apply to a veterinary food-animal drug retailer or wholesaler if the board shall find that sufficient, qualified supervision is employed by the veterinary food-animal drug retailer or wholesaler to adequately safeguard and protect the public health, nor shall Section 4051 apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

(b) An individual employed by a veterinary food-animal drug retailer or wholesaler may apply for an exemption from Section 4051. In order to obtain and maintain that exemption, the individual shall meet the following requirements:

(1) He or she shall be a high school graduate or possess a general education development equivalent.

(2) He or she shall have a minimum of one year of paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of state and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of state and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board may, by regulation, require training programs to include additional material.

(6) The board shall not issue a certificate of exemption until the applicant provides proof of completion of the required training to the board.

(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or an individual in possession of a certificate of exemption on its premises.

(d) Only a pharmacist or an individual in possession of a certificate of exemption shall prepare and affix the label to veterinary food-animal drugs.

(e) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative before January 1, 2006, amends or repeals that date.

4053. (a) Subdivision (a) of Section 4051 shall not apply to a veterinary food-animal drug retailer or wholesaler that employs a designated representative to adequately safeguard and protect the public health, nor shall Section 4051 apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

(b) An individual may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development equivalent.

(2) He or she shall have a minimum of one year of paid work experience, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.

(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.

(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.

(e) This section shall become operative on January 1, 2006.

4053.1. (a) Certificates of exemption issued or renewed pursuant to Section 4053 prior to January 1, 2005, shall remain valid until their expiration date or until January 1, 2007, whichever date is earlier.

(b) Individuals in possession of a current and valid certificate of exemption shall be issued a license as a designated representative if the individual satisfies the requirements of Section 4053 and pays the fee required by subdivision (i) of Section 4400.

(c) This section shall become inoperative and be repealed on January 1, 2007, unless a later enacted statute, that becomes operative on or before December 31, 2006, amends or repeals that date.

4054. Section 4051 shall not apply to a manufacturer or wholesaler that provides dialysis drugs and devices directly to patients.

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through an exemptee, the exemptee may sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered.

Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

Effective January 1, 2006

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative may sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered.

Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(g) This section shall become operative on January 1, 2006.

4060. No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, or a pharmacist pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, or a physician assistant to order his or her own stock of dangerous drugs and devices.

4068. (a) Notwithstanding any provision of this chapter, a prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply:

(1) The hospital pharmacy is closed and there is no pharmacist available in the hospital.

(2) The dangerous drug is acquired by the hospital pharmacy.

(3) The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens.

(4) The hospital pharmacy retains the dispensing information and, if the drug is a schedule II or schedule III controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code.

(5) The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient.

(6) The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply.

(7) The prescriber shall ensure that the label on the drug contains all the information required by Section 4076.

(b) The prescriber shall be responsible for any error or omission related to the drugs dispensed.

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or exemptee-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or exemptee-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or exemptee-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

Effective January 1, 2006

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit,

registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) This section shall become operative on January 1, 2006.

4084. (a) When a board inspector finds, or has probable cause to believe, that any dangerous drug or dangerous device is adulterated or counterfeit, the board inspector shall affix a tag or other marking to that dangerous drug or dangerous device. The board inspector shall give notice to the person that the dangerous drug or dangerous device bearing the tag or marking has been embargoed.

(b) When a board inspector has found that an embargoed dangerous drug or dangerous device is not adulterated or counterfeit, a board inspector shall remove the tag or other marking.

(c) A board inspector may secure a sample or specimen of a dangerous drug or dangerous device. If the board inspector obtains a sample prior to leaving the premises, the board inspector shall leave a receipt describing the sample.

(d) For the purposes of this article "counterfeit" shall have the meaning defined in Section 109905 of the Health and Safety Code.

(e) For the purposes of this article "adulterated" shall have the meaning defined in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

4085. (a) It is unlawful for any person to remove, sell, or dispose of an embargoed dangerous drug or dangerous device without permission of the board.

(b) When a board inspector has reasonable cause to believe, that the embargo will be violated, a board inspector may remove the embargoed dangerous drug or dangerous device from the premises.

4086. (a) If a dangerous drug or dangerous device is alleged to be adulterated or counterfeit, the board shall commence proceedings in the superior court in whose jurisdiction the dangerous drug or dangerous device is located, for condemnation of the dangerous drug or dangerous device.

(b) If the court finds that an embargoed dangerous drug or dangerous device is adulterated or counterfeit, the dangerous drug or dangerous device shall, after entry of the judgment, be destroyed at the expense of the claimant or owner, under the supervision of the board. All court costs and fees and all reasonable costs incurred by the board in investigating and prosecuting the action, including, but not limited to, the costs of storage and testing, shall be paid by the claimant or owner of the dangerous drug or dangerous device.

(c) A superior court of this state may condemn any dangerous drug or dangerous device pursuant to this article. In the absence of an order, the dangerous drug or dangerous device may be destroyed under the supervision of the board who has the written consent of the owner, his or her attorney, or authorized representative. If the board cannot ascertain ownership of the dangerous drug or dangerous device within 30 days of establishing an embargo, the board may destroy the dangerous drug or dangerous device.

4100. (a) Within 30 days after changing his or her address of record with the board or after changing his or her name according to law, every pharmacist, intern pharmacist, technician, or exemptee shall notify the executive officer of the board of the change of address or change of name.

(b) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

Effective January 1, 2006

4100. (a) Within 30 days after changing his or her address of record with the board or after changing his or her name according to law, a pharmacist, intern pharmacist, technician, or designated representative shall notify the executive officer of the board of the change of address or change of name.

(b) This section shall become operative on January 1, 2006.

4101. (a) A pharmacist who takes charge of, or acts as pharmacist-in-charge of a pharmacy or other entity licensed by the board, who terminates his or her employment at the pharmacy or other entity, shall notify the board within 30 days of the termination of employment.

(b) An exemptee-in-charge of a wholesaler or veterinary food drug-animal retailer, who terminates his or her employment at that entity shall notify the board within 30 days of the termination of employment.

4105. (a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the exemptee, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

Effective January 1, 2006

4105. (a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) This section shall become operative on January 1, 2006.

4107. The board may not issue more than one site license to a single premises except to issue a veterinary food-animal drug retailer license to a wholesaler or to issue a license to compound sterile injectable drugs to a pharmacy. For the purposes of this subdivision, "premises" means a location with its own address and an independent means of ingress and egress.

4111. (a) Except as otherwise provided in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy to any of the following:

(1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.

(2) A person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the permit sought.

(3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership by paragraph (1) or (2).

(b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.

(c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.

(d) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a person licensed on or before August 1, 1981, under the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code) and qualified on or before August 1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, as amended, whose ownership includes persons defined pursuant to paragraphs (1) and (2) of subdivision (a).

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist authorized to issue a drug order pursuant to subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

4114. (a) An intern pharmacist may perform all functions of a pharmacist at the discretion of and under the supervision of a pharmacist whose license is in good standing with the board.

(b) A pharmacist may not supervise more than two intern pharmacists at any one time.

4115. (a) Notwithstanding any other provision of law, a pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, only while assisting, and while under the direct supervision and control of, a pharmacist.

(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty, nor does this section authorize the use of a pharmacy technician to perform tasks specified in subdivision (a) except under the direct supervision and control of a pharmacist.

(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the direct supervision and control of a pharmacist. Any pharmacy that employs a pharmacy technician to perform tasks specified in subdivision (a) shall do so in conformity with the regulations adopted by the board pursuant to this subdivision.

(e) (1) No person shall act as a pharmacy technician without first being registered with the board as a pharmacy technician as set forth in Section 4202.

(2) The registration requirements in paragraph (1) and Section 4202 shall not apply during the first year of employment for a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

(f) (1) The performance of duties by a pharmacy technician shall be under the direct supervision and control of a pharmacist. The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician. A pharmacy technician may perform the duties, as specified in subdivision (a), only under the immediate, personal supervision and control of a pharmacist. Any pharmacist responsible for a pharmacy technician shall be on the premises at all times, and the pharmacy technician shall be within the pharmacist's view. A pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient, or by engaging in other verification procedures that are specifically approved by board regulations.

(2) This subdivision shall not apply to a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility. Notwithstanding the exemption in this subdivision, the requirements of subdivisions (a) and (b) shall apply to a person employed or utilized as a pharmacy technician to assist in the filling of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility.

(g) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, and for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for

each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. No entity employing a pharmacist may discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

(h) Notwithstanding subdivisions (b) and (f), the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. Nothing in this subdivision shall be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (g).

4119.1. (a) A pharmacy may provide pharmacy services to a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 of the Health and Safety Code, through the use of an automated drug delivery system that need not be located at the same location as the pharmacy.

(b) Drugs stored in an automated drug delivery system shall be part of the inventory of the pharmacy providing pharmacy services to that facility, and drugs dispensed from the pharmacy system shall be considered to have been dispensed by that pharmacy.

(c) (1) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs and dangerous devices stored in the automated drug delivery system separate from other pharmacy records.

(2) The pharmacy shall own and operate the automated drug delivery system.

(3) The pharmacy shall provide training regarding the operation and use of the automated drug delivery system to both pharmacy and health facility personnel using the system.

(4) The pharmacy shall operate the automated drug delivery system in compliance with Section 1261.6 of the Health and Safety Code.

(d) The operation of the automated drug delivery system shall be under the supervision of a licensed pharmacist. To qualify as a supervisor for an automated drug delivery system, the pharmacist need not be physically present at the site of the automated drug delivery system and may supervise the system electronically.

(e) Nothing in this section shall be construed to revise or limit the use of automated drug delivery systems as permitted by the board in any licensed health facility other than a facility defined in subdivision (c) or (d), or both, of Section 1250 of the Health and Safety Code.

4126.5. (a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control.

(b) Notwithstanding any other provision of law, a violation of this section by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities may subject the persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

(e) For purposes of subdivision (b) of this section and subdivision (s) of Section 4301, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

4127.7. On and after July 1, 2005, a pharmacy shall compound sterile injectable products from one or more nonsterile ingredients in one of the following environments:

(a) An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.

(b) An ISO class 5 cleanroom.

(c) A barrier isolator that provides an ISO class 5 environment for compounding.

4145. (a) Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use, if one of the following requirements is met:

(1) The person is known to the furnisher and the furnisher has previously been provided a prescription or other proof of a legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment.

(2) Pursuant to authorization by a county, with respect to all of the territory within the county, or a city, with respect to the territory within the city, for the period commencing January 1, 2005, and ending December 31, 2010, a pharmacist may furnish or sell 10 or fewer hypodermic needles or syringes at any one time to a person 18 years of age or older if the pharmacist works for a pharmacy that is registered for the Disease Prevention Demonstration Project pursuant to Chapter 13.5 (commencing with Section 121285) of Part 4 of Division 105 of the Health and Safety Code and the pharmacy complies with the provisions of that chapter.

(b) Notwithstanding any other provision of law, a pharmacist, veterinarian, or person licensed pursuant to Section 4141 may, without a prescription or license, furnish hypodermic needles and syringes for use on animals, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist, veterinarian, or person licensed pursuant to

Section 4141 for use on animals, providing that no needle or syringe shall be furnished to a person who is unknown to the furnisher and unable to properly establish his or her identity.

4146. Repealed

4147. (a) For the purposes of this section, "playground" means any park or outdoor recreational area specifically designed to be used by children that has play equipment installed or any similar facility located on public or private school grounds or county parks.

(b) Any hypodermic needle or syringe that is to be disposed of, shall be contained, treated, and disposed of, pursuant to Part 14 (commencing with Section 117600) of Division 104 of the Health and Safety Code.

(c) It is unlawful to discard or dispose of a hypodermic needle or syringe upon the grounds of a playground, beach, park, or any public or private elementary, vocational, junior high, or high school.

(d) A person who knowingly violates subdivision (c) is guilty of a misdemeanor, and upon conviction shall be punished by a fine of not less than two hundred dollars (\$200) and not more than two thousand dollars (\$2,000), or by imprisonment in a county jail for up to six months, or by both that fine and imprisonment.

(e) Subdivision (c) does not apply to the containment, treatment, and disposal of medical sharps waste from medical care or first aid services rendered on school grounds, nor to the containment, treatment, and disposal of hypodermic needles or syringes used for instructional or educational purposes on school grounds.

4160. (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) The board shall not issue or renew a wholesaler license until the wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee-in-charge. The exemptee-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. A wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be the exemptee-in-charge. A pharmacist may be designated as the exemptee-in-charge.

(e) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

(f) A drug manufacturer licensed by the Food and Drug Administration or pursuant to Section 111615 of the Health and Safety Code that only ships dangerous drugs or dangerous devices of its own manufacture is exempt from this section.

(g) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

Effective January 1, 2006

4160. (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

- (c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.
- (d) The board shall not issue or renew a wholesaler license until the wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. A wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.
- (e) A drug manufacturer licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.
- (f) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a wholesaler.
- (g) This section shall become operative on January 1, 2006.

- 4161.** (a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state at wholesale shall be considered an out-of-state distributor.
- (b) An out-of-state distributor shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.
 - (c) A separate license shall be required for each place of business owned or operated by an out-of-state distributor from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.
 - (d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of an out-of-state distributor license, or within 30 days of a change in the following information:
 - (1) Its agent for service of process in this state.
 - (2) Its principal corporate officers, as specified by the board, if any.
 - (3) Its general partners, as specified by the board, if any.
 - (4) Its owners, if the applicant is not a corporation or partnership.
 - (e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
 - (f) An out-of-state distributor shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.
 - (g) An out-of-state distributor wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.
 - (h) An out-of-state distributor shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for an out-of-state distributor license in this state shall include a license verification from the licensing authority in the applicant's state of residence.
 - (i) The board may not issue or renew an out-of-state distributor license until the out-of-state distributor identifies an exemptee-in-charge and notifies the board in writing of the identity and license number of the exemptee-in-charge.
 - (j) The exemptee-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify

the board of a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be the exemptee-in-charge.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as an out-of-state distributor.

(l) The license fee shall be the fee specified in subdivision (f) of Section 4400.

(m) A pharmacy that meets the requirements of Section 4001.2, as added by Senate Bill 1149 of the 2003-04 Regular Session, including any subsequent amendment thereto, shall not be considered an out-of-state distributor for purposes of this section.

(n) This section shall remain in effect only until January 1, 2006, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2006, deletes or extends that date.

Effective January 1, 2006

4161. (a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.

(b) A nonresident wholesaler shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.

(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:

- (1) Its agent for service of process in this state.
- (2) Its principal corporate officers, as specified by the board, if any.
- (3) Its general partners, as specified by the board, if any.
- (4) Its owners if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.

(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.

(i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.

(k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an

amount not to exceed the annual fee for renewal of a license to conduct business as a nonresident wholesaler.

(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

(m) A pharmacy that meets the requirements of Section 4001.2, as added by Senate Bill 1149 of the 2003-04 Regular Session, including any subsequent amendment thereto, shall not be considered a nonresident wholesaler for purposes of this section.

(n) This section shall become operative January 1, 2006.

4162. (a) (1) An applicant for the issuance or renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) if the annual gross receipts of the previous tax year for the wholesaler is ten million dollars (\$10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars (\$25,000).

(3) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler, shall not be required to post a surety bond as provided in paragraph (1).

(4) For licensees subject to paragraph (2) or (3), the board may require a bond up to one hundred thousand dollars (\$100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000) for each site to be licensed, or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purpose of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars (\$10,000,000) or less in which the surety bond shall be twenty-five thousand dollars (\$25,000).

(3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars (\$100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, 2011, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.

4163. (a) No manufacturer or wholesaler shall furnish any dangerous drugs or dangerous devices to any unauthorized persons.

(b) No person shall acquire dangerous drugs or dangerous devices from a person not authorized by law to possess or furnish those dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

Effective January 1, 2007

4163. (a) A manufacturer or wholesaler may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) A wholesaler or pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(d) A wholesaler or pharmacy may not acquire a dangerous drug without receiving a pedigree.

(e) This section shall become operative on January 1, 2007.

4163.5. The board may extend the date for compliance with the requirement for a pedigree set forth in Section 4163 until January 1, 2008, if it determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state. A determination by the board to extend the deadline for providing pedigrees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

4163.6. If the Legislature determines that it is not yet economically and technically feasible for pharmacies to implement electronic technologies to track the distribution of dangerous drugs within the state, the Legislature may extend the date for compliance with the requirement for a pedigree for pharmacies set forth in Section 4163 until January 1, 2009.

4164. (a) All wholesalers licensed by the board and all manufacturers who distribute controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all sales of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.

(b) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

Effective January 1, 2006

4164. (a) A wholesaler licensed by the board that distributes controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all sales of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.

(b) Each wholesaler shall develop and maintain a system for tracking individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. The system shall be capable of identifying purchases of any dangerous drug at preferential or contract prices by customers that vary significantly from prior ordering patterns for the same customer, including by identifying purchases in the preceding 12 calendar months by that customer or similar customers and identifying current purchases that exceed prior purchases by either that customer or similar customers by a factor of 20 percent. Each wholesaler shall have the tracking system required by this subdivision in place no later than January 1, 2006.

(c) Upon written, oral, or electronic request by the board, a wholesaler shall furnish data tracked pursuant to subdivision (b) to the board in written, hardcopy, or electronic form. The board shall specify the dangerous drugs, the customers, or both the dangerous drugs and customers for which data are to be furnished, and the wholesaler shall have 30 calendar days to comply with the request.

(d) As used in this section, "preferential or contract prices" means and refers to purchases by contract of dangerous drugs at prices below the market wholesale price for those drugs.

(e) This section shall become operative on January 1, 2006.

4165. A wholesaler licensed by the board who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer.

4166. (a) Any wholesaler that uses the services of any carrier, including, but not limited to, the United States Postal Service or any common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.

(b) Nothing in this section is intended to affect the liability of a wholesaler or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.

4168. A county or municipality may not issue a business license for any establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board. For purposes of this section, an "establishment" is the licensee's physical location in California.

4169. (a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy, in violation of Section 4163.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Health Services.

(e) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

Effective January 1, 2007

4169. (a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section or of subdivision (c) or (d) of Section 4163 may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) Amounts due from any person under this section shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) This section shall not apply to a pharmaceutical manufacturer licensed by the Food and Drug Administration or by the State Department of Health Services.

(e) This section shall become operative on January 1, 2007.

4170.5. (a) Veterinarians in a veterinary teaching hospital operated by an accredited veterinary medical school may dispense and administer dangerous drugs and devices and controlled substances from a common stock.

(b) The veterinary teaching hospital shall designate a pharmacist to be responsible for ordering the drugs for the common stock and the designated pharmacist-in-charge shall be professionally responsible to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, and dispensing occur in a manner that is consistent with the promotion and protection of the health and safety of the public.

(c) The veterinary teaching hospital's pharmacist-in-charge shall develop policies, procedures, and guidelines that recognize the unique relationship between the institution's pharmacists and veterinarians in the control, management, dispensation, and administration of drugs.

(d) The board may inspect a veterinary teaching hospital dispensing or administering drugs pursuant to this section.

4196. (a) No person shall conduct a veterinary food-animal drug retailer in the State of California unless he or she has obtained a license from the board. A license shall be required for each veterinary food-animal drug retailer owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a veterinary food-animal drug

retailer in more than one location. The license shall be renewed annually and shall not be transferable.

(b) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct a veterinary food-animal drug retailer.

(c) No person other than a pharmacist, an intern pharmacist, an exempt person, an authorized officer of the law, or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the permit issued by the board pursuant to Section 4041, wherein veterinary food-animal drugs are stored, possessed, or repacked. A pharmacist or exemptee shall be responsible for any individual who enters the veterinary food-animal drug retailer for the purpose of performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the veterinary food-animal drug retailer.

(d) The board shall not issue or renew a veterinary food-animal retailer license until the veterinary food-animal drug retailer designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee. The exemptee-in-charge shall be responsible for the veterinary food-animal drug retailer's compliance with state and federal laws governing veterinary food-animal drug retailers. Each veterinary food-animal drug retailer shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be the exemptee-in-charge. A pharmacist may be designated as the exemptee-in-charge.

(e) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

(f) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

4196. (a) No person shall conduct a veterinary food-animal drug retailer in the State of California unless he or she has obtained a license from the board. A license shall be required for each veterinary food-animal drug retailer owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a veterinary food-animal drug retailer in more than one location. The license shall be renewed annually and shall not be transferable.

(b) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct a veterinary food-animal drug retailer.

(c) No person other than a pharmacist, an intern pharmacist, a designated representative, an authorized officer of the law, or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the permit issued by the board pursuant to Section 4041, wherein veterinary food-animal drugs are stored, possessed, or repacked. A pharmacist or designated representative shall be responsible for any individual who enters the veterinary food-animal drug retailer for the purpose of performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the veterinary food-animal drug retailer.

(d) The board shall not issue or renew a veterinary food-animal retailer license until the veterinary food-animal drug retailer identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. The designated representative-in-charge shall be responsible for the veterinary food-animal drug retailer's compliance with state and federal laws governing veterinary food-animal drug retailers. Each veterinary food-animal drug retailer shall identify, and notify the board of, a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-

charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.

(e) For purposes of this section, designated representative-in-charge means a person granted a designated representative license pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

(f) This section shall become operative on January 1, 2006.

4200.1. (a) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination four times, and may take the Multi-State Pharmacy Jurisprudence Examination for California four times.

(b) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California four additional times each if he or she successfully completes, at minimum, 16 additional semester units of education in pharmacy as approved by the board.

(c) The applicant shall comply with the requirements of Section 4200 for each application for reexamination made pursuant to subdivision (b).

(d) An applicant may use the same coursework to satisfy the additional educational requirement for each examination under subdivision (b), if the coursework was completed within 12 months of the date of his or her application for reexamination.

(e) For purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004, as a failing score on both the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California.

(f) From January 1, 2004, to July 1, 2006, inclusive, the board shall collect data on the applicants who are admitted to, and take, the licensure examinations required by Section 4200. The board shall report to the Joint Committee on Boards, Commissions, and Consumer Protection before September 1, 2006, regarding the impact on those applicants of the examination limitations imposed by this section. The report shall include, but not be limited to, the following information:

(1) The number of applicants taking the examination and the number who fail the examination for the fourth time.

(2) The number of applicants who, after failing the examination for the fourth time, complete a pharmacy studies program in California or another state to satisfy the requirements of this section and who apply to take the licensure examination required by Section 4200.

(3) To the extent possible, the school from which the applicant graduated and the school's location and the pass/fail rates on the examination for each school.

(g) This section shall remain in effect only until January 1, 2008, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2008, deletes or extends that date.

4207. (a) Upon receipt of an application for a license and the applicable fee, the board shall make a thorough investigation to determine whether the applicant is qualified for the license being sought. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license that may affect the public welfare.

(b) The board shall not investigate matters connected with the operation of a premises other than those matters solely related to the furnishing of dangerous drugs or dangerous devices that might adversely affect the public welfare.

(c) The board shall deny an application for a license if the applicant does not qualify for the license being sought.

(d) Notwithstanding any other provision of law, the board may request any information it deems necessary to complete the application investigation required by this section, and a request for information that the board deems necessary in carrying out this section in any application or

related form devised by the board shall not be required to be adopted by regulation pursuant to the Administrative Procedures Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

4208. (a) At the discretion of the board, an intern pharmacist license may be issued for a period of:

(1) One to six years to a person who is currently enrolled in a school of pharmacy recognized by the board.

(2) Two years to a person who is a graduate of a school of pharmacy recognized by the board and who has applied to become licensed as a pharmacist in California.

(3) Two years to a foreign graduate who has met educational requirements described in paragraphs (1) and (2) of subdivision (a) of Section 4200.

(4) One year to a person who has failed the pharmacist licensure examination four times and has reenrolled in a school of pharmacy to satisfy the requirements of Section 4200.1.

(b) The board may issue an intern pharmacist license to an individual for the period of time specified in a decision of reinstatement adopted by the board.

(c) An intern pharmacist shall notify the board within 30 days of any change of address.

(d) An intern pharmacist whose license has been issued pursuant to paragraph (1) or paragraph (4) of subdivision (a) shall return his or her license, by registered mail, within 30 days of no longer being enrolled in a school of pharmacy. The intern pharmacist license will be canceled by the board. Notwithstanding subdivision (c), an intern pharmacist license may be reinstated if the student reenrolls in a school of pharmacy recognized by the board to fulfill the education requirements of paragraphs (1) to (4), inclusive, of subdivision (a) of Section 4200.

4209. (a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.

(2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.

(b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Gross immorality.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer

(including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering or offering to sell, furnish, give away, or administer any controlled substance to an addict.

(j) The violation of any of the statutes of this state or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs

obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

Effective January 1, 2006

4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

- (a) Gross immorality.
- (b) Incompetence.
- (c) Gross negligence.
- (d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.
- (e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.
- (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.
- (g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
- (h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.
- (i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering or offering to sell, furnish, give away, or administer any controlled substance to an addict.
- (j) The violation of any of the statutes of this state or of the United States regulating controlled substances and dangerous drugs.
- (k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.
- (l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions,

and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code.

(t) This section shall become operative on January 1, 2006.

4305.5. (a) Any person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, shall notify the board within 30 days of the termination of employment of any pharmacist or exemptee who takes charge of, or acts as manager of the licensee. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(b) Any person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, who willfully fails to notify the board of the termination of employment of any pharmacist or exemptee who takes charge of, or acts as manager of the licensee, and who continues to operate the licensee in the absence of a pharmacist or an exemptee approved for that location, shall be subject to summary suspension or revocation of his or her license to conduct a wholesaler or veterinary food-animal drug retailer. (c) Any pharmacist or exemptee who takes charge of, or acts as manager of a wholesaler or veterinary food-animal drug retailer, who terminates his or her employment at the licensee, shall notify the board within 30 days of the

termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(d) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

Effective January 1, 2006

4305.5. (a) A person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, shall notify the board within 30 days of the termination of employment of the designated representative-in-charge. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(b) A person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, who willfully fails to notify the board of the termination of employment of the designated representative-in-charge, and who continues to operate the licensee in the absence of the designated representative-in-charge for that location, shall be subject to summary suspension or revocation of his or her license to conduct a wholesaler or veterinary food-animal drug retailer.

(c) A designated representative-in-charge of a wholesaler or veterinary food-animal drug retailer, who terminates his or her employment at the licensee, shall notify the board within 30 days of the termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(d) This section shall become operative on January 1, 2006.

4311. (a) Any license issued by the board, or the holder thereof, shall be suspended automatically during any time that the person is incarcerated after conviction of a felony, regardless of whether the conviction has been appealed. The board, immediately upon receipt of a certified copy of a record of a criminal conviction, shall determine whether the person has been automatically suspended by virtue of incarceration pursuant to a felony conviction and, if so, the duration of that suspension. The board shall notify the person so suspended of the suspension and that the person has a right to request a hearing, solely as to whether he or she is incarcerated pursuant to a felony conviction, in writing at that person's address of record with the board and at the facility in which the person is incarcerated.

(b) In addition to any suspension under subdivision (a), the board shall summarily suspend any license issued by the board where a conviction of the holder of the license meets the requirements of paragraphs (1) and (2).

(1) A felony that was either of the following:

(A) Committed in the course of a business or practice for which the board issues a license.

(B) Committed in a manner that a client, customer, or patient of the licensee was a victim.

(2) Where an element of the offense involves either of the following:

(A) The specific intent to deceive, defraud, steal, or make a false statement.

(B) The illegal sale or possession for sale of or trafficking in any controlled substance.

(3) The suspension shall continue until the time for appeal has elapsed, if no appeal is taken, or until the judgment of conviction has been affirmed on appeal or has otherwise become final, and until further order of the board.

(4) The board shall immediately send notice in writing of the suspension to the licensee, or the holder of any other board-issued license, at his or her address of record and, if incarcerated at the time, at the facility in which the person is incarcerated. The notice shall include notification of that person's right to elect to have the issue of penalty heard as provided in paragraph (2) of subdivision (d), and of the right to request a hearing to contest the summary suspension. Any request for a hearing under this paragraph must be received by the board within 15 days following receipt of the notice provided for by this paragraph.

(5) The hearing shall be before an administrative law judge, a committee of the board sitting with an administrative law judge, or the board sitting with an administrative law judge, at the

board's discretion, and shall be subject to review by the board, at its discretion. The hearing shall be limited to (A) whether there has been a felony conviction as stated in the board's notice, and (B) whether the conviction meets the criteria of this subdivision, except where the licensee chooses to proceed as provided by paragraph (2) of subdivision (d), or where the board has also filed and served an accusation as provided in Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code and given notice of the hearing as required by that chapter; provided that if an accusation under Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code is also to be heard, only an administrative law judge sitting alone or the board, sitting with an administrative law judge, may hear the case. (c) In addition to any suspension under subdivision (a), the board shall also suspend any license issued by the board, or the holder thereof, if the board determines that the felony conviction of the holder of the license is substantially related to the qualifications, functions, or duties of the licensee.

(1) Notice of the board's determination shall be sent to the licensee, or the holder thereof, at that person's address of record with the board and, if the person is incarcerated at the time, the facility in which the person is incarcerated. The notice shall advise the person that the license shall be suspended without hearing unless, within 15 days following receipt of the notice, a written request for hearing is delivered to the board.

(2) Upon receipt of a timely request for hearing, a notice of hearing shall be sent to the person at least 10 days before the date scheduled for the hearing. The notice of hearing shall include notification of that person's right to elect to have the issue of penalty heard as provided in paragraph (2) of subdivision (d).

(3) The hearing to determine whether a felony conviction is substantially related for purposes of an interim suspension under this subdivision shall be separate from any hearing on an accusation under the Administrative Procedure Act, except where the licensee elects to proceed under paragraph (2) of subdivision (d), or where the board has filed and served an accusation as provided by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code and given notice of hearing as required by that chapter. The hearing on whether the felony conviction is substantially related shall be heard either by an administrative law judge sitting alone, by a committee of the board sitting with an administrative law judge, or by the board sitting with an administrative law judge, at the board's discretion, and shall be subject to review by the board, at its discretion. However, if an accusation under Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code is also to be heard, only an administrative law judge sitting alone or the board, sitting with an administrative law judge, may hear the case. Except where a person proceeds under paragraph (2) of subdivision (d), or the board proceeds with an accusation at the same time, any suspension imposed under this subdivision shall continue until an accusation is filed under Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code and a final decision is rendered by the board.

(4) A conviction of any crime referred to in Section 4301, or for violation of Section 187, 261, or 288 of the Penal Code, shall be conclusively presumed to be substantially related to the qualifications, functions, or duties of a licensee of the board. Upon its own motion or for good cause shown the board may decline to impose a suspension under this subdivision or may set aside a suspension previously imposed when it appears to be in the interest of justice to do so, with due regard to maintaining the integrity of and confidence in the practice of pharmacy and the handling of dangerous drugs and devices.

(d) (1) Discipline may be ordered in accordance with Section 4300 or an application denied when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, setting aside the verdict of guilty, or dismissing

the accusation, complaint, information, or indictment. (2) The issue of penalty shall be heard by an administrative law judge sitting alone or with a committee of the board or with the board itself, at the board's discretion, and any decision shall be subject to review by the board, at its discretion. The hearing shall not be held until the judgment of conviction has become final or, irrespective of a subsequent order under Section 1203.4 of the Penal Code, an order granting probation has been made suspending the imposition of sentence, provided that a licensee may, at his or her option, elect to have the issue of penalty decided before those time periods have elapsed. Where the licensee so elects, the issue of penalty shall be heard in the manner described in this section at the hearing to determine whether the conviction was substantially related to the qualifications, functions, or duties of the licensee. If the conviction of a licensee who has made this election is overturned on appeal, any discipline ordered pursuant to this section shall automatically cease. Nothing in this subdivision shall prohibit the board from pursuing disciplinary action based on any cause, including the facts underlying the conviction, other than the overturned conviction.

(3) The record of the proceedings resulting in the criminal conviction, including a transcript of any testimony taken in connection with the proceeding, may be received in evidence in any administrative proceeding to the extent the testimony would otherwise be admissible under Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. A certified copy of the criminal conviction shall be conclusive proof of the fact of the conviction.

(e) Other provisions of this chapter setting forth procedures for the suspension or revocation of a license issued by the board shall not apply to proceedings conducted pursuant to this section, except as specifically provided in this section.

(f) For purposes of this section, a crime is a felony if it is specifically declared to be so or is made a felony by subdivision (a) of Section 17 of the Penal Code, unless it is charged as a misdemeanor pursuant to paragraph (4) or (5) of subdivision (b) of Section 17 of the Penal Code, irrespective of whether in a particular case the crime may be considered a misdemeanor as a result of postconviction proceedings. For purposes of this section, a felony also includes a conviction under federal law, or the law of any other state of the United States, of the District of Columbia, or of any territory or possession of the United States. A conviction includes a plea or verdict of guilty or a conviction following a plea of nolo contendere.

(g) The board may delegate the authority to issue a suspension under subdivision (a) or (b) or a notice of suspension under subdivision (c) to the executive officer of the board.

4331. (a) Any person who is neither a pharmacist nor an exemptee and who takes charge of a wholesaler or veterinary food-animal drug retailer or who dispenses a prescription or furnishes dangerous devices except as otherwise provided in this chapter is guilty of a misdemeanor.

(b) Any person who has obtained a license to conduct a veterinary food-animal drug retailer and who fails to place in charge of that veterinary food-animal drug retailer a pharmacist or exemptee, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or exemptee, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(c) Any person who has obtained a license to conduct a wholesaler and who fails to place in charge of that wholesaler a pharmacist or exemptee, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a pharmacist or exemptee, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(d) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

Effective January 1, 2006

4331. (a) A person who is neither a pharmacist nor a designated representative and who takes charge of a wholesaler or veterinary food-animal drug retailer or who dispenses a prescription or

furnishes dangerous devices except as otherwise provided in this chapter is guilty of a misdemeanor.

(b) A person who has obtained a license to conduct a veterinary food-animal drug retailer and who fails to place in charge of that veterinary food-animal drug retailer a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(c) A person who has obtained a license to conduct a wholesaler and who fails to place in charge of that wholesaler a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(d) This section shall become operative on January 1, 2006.

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars (\$340) and may be increased to four hundred dollars (\$400).

(b) The fee for a nongovernmental pharmacy or medical device retailer annual renewal shall be one hundred seventy-five dollars (\$175) and may be increased to two hundred fifty dollars (\$250).

(c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars (\$155) and may be increased to one hundred eighty-five dollars (\$185).

(d) The fee for regrading an examination shall be seventy-five dollars (\$75) and may be increased to eighty-five dollars (\$85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars (\$115) and may be increased to one hundred fifty dollars (\$150).

(f) The fee for a wholesaler license and annual renewal shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600).

(g) The fee for a hypodermic license and renewal shall be ninety dollars (\$90) and may be increased to one hundred twenty-five dollars (\$125).

(h) The fee for application and investigation for an exemptee license under Section 4053 shall be seventy-five dollars (\$75) and may be increased to one hundred dollars (\$100), except for a veterinary food-animal drug retailer exemptee, for whom the fee shall be one hundred dollars (\$100).

(i) The fee for an exemptee license and annual renewal under Section 4053 shall be one hundred ten dollars (\$110) and may be increased to one hundred fifty dollars (\$150), except that the fee for the issuance of a veterinary food-animal drug retailer exemptee license shall be one hundred fifty dollars (\$150), for renewal one hundred ten dollars (\$110), which may be increased to one hundred fifty dollars (\$150), and for filing a late renewal fifty-five dollars (\$55).

(j) The fee for an out-of-state drug distributor's license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600).

(k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(l) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.

(m) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars (\$165) and may be increased to one hundred seventy-five dollars (\$175).

- (n) The fee for an intern license or extension shall be sixty-five dollars (\$65) and may be increased to seventy-five dollars (\$75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars (\$20).
- (o) The board may, by regulation, provide for the waiver or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding regular renewal date.
- (p) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars (\$30).
- (q) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars (\$60) and may be increased to one hundred dollars (\$100).
- (r) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.
- (s) The fee for any applicant for a clinic permit is three hundred forty dollars (\$340) and may be increased to four hundred dollars (\$400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars (\$175) and may be increased to two hundred fifty dollars (\$250) for each permit.
- (t) The board shall charge a fee for the processing and issuance of a registration to a pharmacy technician and a separate fee for the biennial renewal of the registration. The registration fee shall be twenty-five dollars (\$25) and may be increased to fifty dollars (\$50). The biennial renewal fee shall be twenty-five dollars (\$25) and may be increased to fifty dollars (\$50).
- (u) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars (\$400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars (\$250).
- (v) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars (\$30).
- (w) This section shall become inoperative and is repealed on January 1, 2006, unless a later enacted statute, that becomes operative on or before January 1, 2006, amends or repeals that date.

Effective January 1, 2006

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided is that fixed by the board according to the following schedule:

- (a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars (\$340) and may be increased to four hundred dollars (\$400).
- (b) The fee for a nongovernmental pharmacy annual renewal shall be one hundred seventy-five dollars (\$175) and may be increased to two hundred fifty dollars (\$250).
- (c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars (\$155) and may be increased to one hundred eighty-five dollars (\$185).
- (d) The fee for regrading an examination shall be seventy-five dollars (\$75) and may be increased to eighty-five dollars (\$85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.
- (e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars (\$115) and may be increased to one hundred fifty dollars (\$150).
- (f) The fee for a wholesaler license and annual renewal shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600).
- (g) The fee for a hypodermic license and renewal shall be ninety dollars (\$90) and may be increased to one hundred twenty-five dollars (\$125).
- (h) The fee for application and investigation for a designated representative license issued pursuant to Section 4053 shall be seventy-five dollars (\$75) and may be increased to one hundred

dollars (\$100), except for a veterinary food-animal drug retailer designated representative, for whom the fee shall be one hundred dollars (\$100).

(i) The fee for a designated representative license and annual renewal under Section 4053 shall be one hundred ten dollars (\$110) and may be increased to one hundred fifty dollars (\$150), except that the fee for the issuance of a veterinary food-animal drug retailer designated representative license shall be one hundred fifty dollars (\$150), for renewal one hundred ten dollars (\$110), which may be increased to one hundred fifty dollars (\$150), and for filing a late renewal fifty-five dollars (\$55).

(j) The fee for a nonresident wholesaler's license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600).

(k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(l) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.

(m) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars (\$165) and may be increased to one hundred seventy-five dollars (\$175).

(n) The fee for an intern license or extension shall be sixty-five dollars (\$65) and may be increased to seventy-five dollars (\$75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars (\$20).

(o) The board may, by regulation, provide for the waiver or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding regular renewal date.

(p) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars (\$30).

(q) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars (\$60) and may be increased to one hundred dollars (\$100).

(r) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(s) The fee for any applicant for a clinic permit is three hundred forty dollars (\$340) and may be increased to four hundred dollars (\$400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars (\$175) and may be increased to two hundred fifty dollars (\$250) for each permit.

(t) The board shall charge a fee for the processing and issuance of a registration to a pharmacy technician and a separate fee for the biennial renewal of the registration. The registration fee shall be twenty-five dollars (\$25) and may be increased to fifty dollars (\$50). The biennial renewal fee shall be twenty-five dollars (\$25) and may be increased to fifty dollars (\$50).

(u) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars (\$400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars (\$250).

(v) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars (\$30).

(w) This section shall become operative on January 1, 2006.

4409. At the time a pharmacy license is renewed pursuant to subdivision (a) of Section 4110 or a pharmacist license is renewed pursuant to Section 4401, the pharmacy or pharmacist may make a contribution of at least twenty-five dollars (\$25), to be submitted to the board, for the sole purpose of funding the California Pharmacist Scholarship and Loan Repayment Program

established pursuant to Article 2 (commencing with Section 128198) of Chapter 3 of Part 3 of Division 107 of the Health and Safety Code. The contribution submitted pursuant to this section shall be paid into the State Treasury and credited to the California Pharmacist Scholarship and Loan Repayment Program Fund established pursuant to Section 128198.5 of the Health and Safety Code.

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11150. No person other than a physician, dentist, podiatrist, or veterinarian, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 of the Business and Professions Code, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

11159.1. An order for controlled substances furnished to a patient in a clinic which has a permit issued pursuant to Article 13 (commencing with Section 4180) of Chapter 9 of Division 2 of the Business and Professions Code, except an order for a Schedule II controlled substance, shall be exempt from the prescription requirements of this article and shall be in writing on the patient's record, signed by the prescriber, dated, and shall state the name and quantity of the controlled substance ordered and the quantity actually furnished. The record of the order shall be maintained as a clinic record for a minimum of seven years. This section shall apply only to a clinic that has obtained a permit under the provisions of Article 13 (commencing with Section 4180) of Chapter 9 of Division 2 of the Business and Professions Code.

Clinics that furnish controlled substances shall be required to keep a separate record of the furnishing of those drugs which shall be available for review and inspection by all properly authorized personnel.

11161. (a) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation of Section 11153, 11154, 11156, 11157, 11170, 11173, 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5, 11379, 11379.5, or 11379.6, the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, upon the motion of a law enforcement agency which is supported by reasonable cause, issue an order which requires the practitioner to surrender to the clerk of the court all triplicate prescription blanks or controlled substance prescription forms in the practitioner's possession at a time set in the order. Except as provided in subdivisions (b) and (e) of this section, the order shall remain in effect until further order of the court. Any practitioner possessing prescription blanks in violation of the order is guilty of a misdemeanor.

(b) The order provided by subdivision (a) shall be vacated if the court or magistrate finds that the underlying violation or violations are not supported by reasonable cause at a hearing held within two court days after the practitioner files and personally serves upon the prosecuting attorney and the law enforcement agency that obtained the order, a notice of motion to vacate the order with any affidavits on which the practitioner relies. At the hearing, the burden of proof, by a preponderance of the evidence, is on the prosecution. Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to

surrender all triplicate prescription blanks or controlled substance prescription forms with supporting affidavits, the sworn complaint together with any documents or reports incorporated by reference thereto which, if based on information and belief, state the basis for the information, or any other documents of similar reliability as well as affidavits and counter affidavits submitted by the prosecution and defense. Granting of the motion to vacate the order is no bar to prosecution of the alleged violation or violations.

(c) The defendant may elect to challenge the order issued under subdivision (a) at the preliminary examination. At that hearing, the evidence shall be limited to that set forth in subdivision (b) and any other evidence otherwise admissible at the preliminary examination.

(d) If the practitioner has not moved to vacate the order issued under subdivision (a) by the time of the preliminary examination and he or she is held to answer on the underlying violation or violations, the practitioner shall be precluded from afterwards moving to vacate the order. If the defendant is not held to answer on the underlying charge or charges at the conclusion of the preliminary examination, the order issued under subdivision (a) shall be vacated.

(e) Notwithstanding subdivision (d), any practitioner who is diverted pursuant to Chapter 2.5 (commencing with Section 1000) of Title 7 of Part 2 of the Penal Code may file a motion to vacate the order issued under subdivision (a).

(f) This section shall become operative on November 1, 2004.

11162.1. (a) The prescription forms for controlled substances shall be printed with the following features:

- (1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.
- (2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."
- (3) A chemical void protection that prevents alteration by chemical washing.
- (4) A feature printed in thermo-chromic ink.
- (5) An area of opaque writing so that the writing disappears if the prescription is lightened.
- (6) A description of the security features included on each prescription form.
- (7) (A) Six quantity checkoff boxes shall be printed on the form and the following quantities shall appear: 1-24 25-49 50-74 75-100 101-150 151 and over.
(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.
- (8) Prescription blanks shall either (A) contain a statement printed on the bottom of the prescription blank that the "Prescription is void if more than one controlled substance prescription is written per blank" or (B) contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."
- (9) The preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.
- (10) A check box indicating the prescriber's order not to substitute.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

- (c) (1) A prescriber designated by a licensed health care facility may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a).
- (2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility preprinted on the form.

- (3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.
- (4) (A) Except as provided in subparagraph (B), the designated prescriber shall maintain a record of the prescribers to whom controlled substance prescription forms are issued, which record shall include the name, category of licensure, license number, federal controlled substance registration number, and the quantity of controlled substance prescription forms issued to each prescriber and shall be maintained in the health facility for three years.
- (B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to the requirements set forth in subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.
- (d) This section shall become operative on July 1, 2004.

11190. (a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:

- (1) The name and address of the patient.
- (2) The date.
- (3) The character, including the name and strength, and quantity of controlled substances involved.
- (b) The prescriber's record shall show the pathology and purpose for which the controlled substance was administered or prescribed.
 - (c) (1) For each prescription for a Schedule II or Schedule III controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:
 - (A) Full name, address, gender, and date of birth of the patient.
 - (B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
 - (C) NDC (National Drug Code) number of the controlled substance dispensed.
 - (D) Quantity of the controlled substance dispensed.
 - (E) ICD-9 (diagnosis code), if available.
 - (F) Date of dispensing of the prescription.
 - (2) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a monthly basis in either hardcopy or electronic form.
- (d) This section shall become operative on January 1, 2005.

11207. (a) No person other than a pharmacist as defined in Section 4036 of the Business and Professions Code or an intern pharmacist, as defined in Section 4030 of the Business and Professions Code, who is under the personal supervision of a pharmacist, shall compound, prepare, fill or dispense a prescription for a controlled substance.

(b) Notwithstanding subdivision (a), a pharmacy technician may perform those tasks permitted by Section 4115 of the Business and Professions Code when assisting a pharmacist dispensing a prescription for a controlled substance.

11364. (a) It is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking (1) a controlled substance specified in subdivision (b), (c), or (e), or paragraph (1) of subdivision (f) of Section 11054, specified in

paragraph (14), (15), or (20) of subdivision (d) of Section 11054, specified in subdivision (b) or (c) of Section 11055, or specified in paragraph (2) of subdivision (d) of Section 11055, or (2) a controlled substance which is a narcotic drug classified in Schedule III, IV, or V.

(b) This section shall not apply to hypodermic needles or syringes that have been containerized for safe disposal in a container that meets state and federal standards for disposal of sharps waste.

(c) Pursuant to authorization by a county, with respect to all of the territory within the county, or a city, with respect to the territory within in the city, for the period commencing January 1, 2005, and ending December 31, 2010, subdivision (a) shall not apply to the possession solely for personal use of 10 or fewer hypodermic needles or syringes if acquired from an authorized source.